NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED Plaintiffs, v. HANDA PHARMACEUTICALS, LLC and JOHN DOE ENTITY Defendants.	:	Civil Action No. 08-3773 (JAP) Civil Action No. 08-5328 (JAP) Civil Action No. 08-5997 (JAP)
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED Plaintiffs, v. ACCORD HEALTHCARE, INC., and INTAS PHARMACEUTICAL LTD., Defendants.	:	Civil Action No. 08-4804 (JAP) Civil Action No. 09-619 (JAP)
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED Plaintiffs, v. BIOVAIL LABORATORIES INTERNATIONAL SRL, BIOVAIL CORPORATION and BTA PHARMACEUTICALS, INC., Defendants.	:	Civil Action No. 09-128 (JAP)

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED Plaintiffs, v. ANCHEN PHARMACEUTICALS, INC. Defendant.	Civil Action No. 10-1835 (JAP)
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED Plaintiffs, v. OSMOTICA PHARMACEUTICAL CORPORATION, Defendant.	Civil Action No. 10-4203 (JAP)
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED Plaintiffs, v. TORRENT PHARMACEUTICALS LIMITED and TORRENT PHARMA INC., Defendants.	Civil Action No. 10-4205 (JAP) Civil Action No. 10-4971 (JAP) **OPINION**

PISANO, District Judge.

Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited (collectively, "Astra") bring these patent infringement actions against Handa Pharmaceuticals, LLC and John Doe Entity (collectively, "Handa"); Accord Healthcare, Inc. and Intas Pharmaceuticals Ltd. (collectively, "Accord"); Biovail Laboratories International SRL, Biovail Corporation, and BTA Pharmaceuticals, Inc. (collectively, "Biovail"); Anchen Pharmaceuticals, Inc. ("Anchen"); Osmotica Pharmaceutical Corporation ("Osmotica"); and Torrent Pharmaceuticals Limited and Torrent Pharma Inc. (collectively, "Torrent"). The patent at issue in this case is Astra's patent, United States Patent No. 5,948,437 (the "'437 Patent"), titled "Pharmaceutical Compositions Using Thiazepine." This patent relates to particular sustained release formulations, the process for preparing the formulations, and methods for treating psychotic states and hyperactivity using the formulations.

Presently before the Court is the parties' request for claim construction. The Court held a *Markman* hearing on November 22, 2010. This Opinion addresses the proper construction of the disputed claim terms.

I. Standards for Claim Construction

In order to prevail in a patent infringement suit, a plaintiff must establish that the patent claim "covers the alleged infringer's product or process." *Markman v. Westview Instrs., Inc.*, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996). Consequently, the first step in an infringement analysis involves determining the meaning and the scope of the claims of the patent. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 988 (Fed. Cir.

1995). Claim construction is a matter of law, *Markman v. Westview Instrs., Inc*., 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd* 517 U.S. 370 (1996); therefore, it is "[t]he duty of the trial judge . . . to determine the meaning of the claims at issue." *Exxon Chem. Patents, Inc. v. Lubrizoil Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995).

In *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), the Federal Circuit emphasized that "[i]t is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." 415 F.3d at 1312 (internal quotations omitted) (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[W]e look to the words of the claims themselves . . . to define the scope of the patented invention"); *Markman*, 52 F.3d at 980 ("The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims."). Generally, the words of a claim are given their "ordinary and customary meaning," which is defined as "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1312-13 (citations omitted). In this regard, the Federal Circuit has noted:

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention--the inventor's lexicography--must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, viz., the patent specification and the prosecution history.

Id. (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed.

Cir.1998)).

In the process of determining the meaning of a claim as understood by a person skilled in the art, a court may look to various sources from which the proper meaning may be discerned. These sources include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.* at 1314. While a court is permitted to turn to extrinsic evidence, such evidence is generally of less significance and less value in the claim construction process. *Id.* at 1317. Extrinsic evidence would include evidence that is outside the patent and prosecution history, and may include expert testimony, dictionaries and treatises. *Id.* The Federal Circuit has noted that caution must be exercised in the use of extrinsic evidence, as this type of evidence may suffer from inherent flaws affecting its reliability in the claim construction analysis. *Id.* at 1319 ("We have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms."). While "extrinsic evidence may be useful to the court, . . . it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence."

II. The Disputed Claim Terms

The parties have identified a number of disputed claim terms in the patent. The Court will address each of these in turn.

1. "A sustained release formulation"

This disputed phrase appears in the preamble of Claim 1 of the '437 Patent. All

parties agree that "sustained release" means the release of the active pharmaceutical ingredient over an extended period of time. The parties also agree that because the remaining claims depend on Claim 1, the construction of this preamble language applies to all claims of the patent. The dispute is whether the preamble is a claim limitation. Astra contends that the preamble should be construed as a claim limitation meaning: "A solid oral dosage form that releases its active pharmaceutical ingredient over an extended period of time." Torrent argues that the preamble should be read to shed light on the meaning of the remaining terms, and terms such as "gelling agent" should be construed in the context of the preamble language. Handa, Biovail, Anchen, and Osmotica ask that the Court address the question of whether the preamble is a claim limitation at a later time. Accord takes no position on the disputed term.

The Court adopts Astra's position on the construction of "A sustained release formulation." It is well settled that a "preamble limits the [claimed] invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). The entire specification of the '437 Patent and all examples are directed to sustained release formulations. The sustained release aspect of the formulations is a fundamental feature of the claimed invention, and thus is an element of the claims. *See Glaxo Wellcome v. Impax Labs. Inc.*, 356 F.3d 1348, 1353 (Fed. Cir. 2004) ("The 'sustained release tablet' phrase recited in the preamble gives life and meaning to the claims, because sustained release is an essential feature of the invention."). Accordingly, the Court adopts Astra's proposed

construction.

2. "a gelling agent"

This disputed phrase appears in all claims of the '437 Patent. Astra, Accord, Biovail, Anchen, and Osmotica propose that the claim be construed as "any substance which forms a gel when in contact with water." Handa counters that the term should mean "an excipient that, when in contact with water, hydrates and swells to form and maintain a gel barrier layer over the surface of the dosage unit, which imparts sustained release of the active ingredient." Torrent contends that the term should be interpreted as such: "An excipient in a sufficient amount that, when in contact with water, hydrates and swells to form and maintain a gel barrier layer over the surface of the dosage unit, which imparts sustained release of the active ingredient. PVP (polyvinylpyrrolidone or Povidone) in an amount of about 15% or less by weight of the core tablet is not a gelling agent."

The Court adopts the position taken by Astra on the construction of "a gelling agent." The patent itself provides a definition of "a gelling agent" consistent with Astra's construction: "The term gelling agent as used herein means any substance, particularly a hydrophilic substance, which forms a gel when in contact with water . . . ." '437 Patent, col. 2, lines 43-45. Handa's proposed construction, on the other hand, limits the term to excipients that hydrate and swell to form and maintain a gel barrier. Although Astra admits that the preferred "gelling agent," hydroxypropyl methylcellulose ("HPMC"), '437 Patent, col. 2, lines 52-53, probably works in the way described by Handa, Nov. 22, 2010 hearing transcript ("Tr.") 24:15-7, the patent itself clearly defines the term in a broader sense.

Torrent's position is essentially the same as that of Handa, but with the added proviso that PVP in an amount of about 15% or less by weight of the core tablet is not a "gelling agent." Torrent points out that the patent makes clear that PVP in that amount is a preferred binder and that the patent, in many instances, describes PVP in that amount as an excipient in addition to a "gelling agent," rather than as a "gelling agent" itself. Tr. 63-66. Nevertheless, Torrent's position fails because it is inconsistent with the express language of the patent, which states: "The term gelling agent as used herein . . . includes such substances as . . . polyvinylpyrrolidone." '437 Patent, col. 2, lines 43-51. Furthermore, even though elsewhere in the patent PVP in an amount of about 15% or less by weight is described as an additional ingredient besides a "gelling agent," nowhere in the intrinsic evidence is there a specific disclaimer of PVP as a "gelling agent." *See SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337, 1347 (Fed. Cir. 2001) (declaring that patents did not cover certain device configurations when they were "specifically recognized and disclaimed" in the patents). Therefore, the Court adopts Astra's proposed claim construction for "a gelling agent."[1]

3. "mixtures thereof"

This disputed phrase appears in Claims 3 through 9 and Claim 13 of the '437 Patent. Astra proposes a construction of the term as "a blend of two or more of the HPMC types (a)-(d) recited in claim 3," which Astra argues is consistent with the term's plain and ordinary

[1] The parties dispute the meaning of the term "a" in the phrase "a gelling agent." The Court finds that construction of this term is not required; its plain and ordinary meaning shall control.

meaning. Handa and Osmotica propose that the term be given its plain and ordinary meaning, with no construction required. Torrent takes no position. Accord, Biovail, and Anchen have proposed that the term mean "a blend, but not a chemical combination, of two or more types of HPMC selected from the group consisting of types (a), (b), (c) and (d) recited in claim 3."

The Court adopts Astra's proposed construction of the term. There is nothing in the intrinsic evidence that warrants reading the term to exclude chemical combinations. The term "mixtures thereof" is well-known and should be given its plain and ordinary meaning. Astra acknowledges that "thereof" limits the mixtures to those including HPMC types (a) through (d) listed in claim 3.

4. "about" with respect to ranges of viscosity, methoxy content, and hydroxypropoxy content

This disputed term appears in Claims 3 through 9 and Claim 13 of the '437 Patent. Astra proposes that the term be defined as "approximately," which Astra argues is consistent with the term's plain and ordinary meaning. Accord contends that the term should mean "equal to, with only minor and inherent variations associated with measurement errors (a person of ordinary skill in the art would recognize the numerical ranges in claim 3 each correspond to specific commercial grades of HPMC that were supplied by Dow Chemical Company in 1996)." Biovail provides the following construction: "A person of ordinary skill in the art would recognize the numerical ranges in claim 3 each correspond to HPMC that were supplied by Dow Chemical Company in 1996, and should be construed as exactly stated with no variation (except perhaps to account for rounding)." Anchen offers this construction:

"Equal to, with only minor variations associated with measurement errors. With respect to 'about 7 to less than 9%,' Anchen proposes that 'about' should be construed to modify only '7' and not 'less than 9%' (Anchen proposes that 'less than 9%' in that claim term means 'less than exactly 9%')." Handa and Osmotica propose the term be given its plain and ordinary meaning, while Torrent takes no position.

The Court adopts Astra's proposed construction of the term. There is nothing in the intrinsic evidence that compels an interpretation of "about" that limits the ranges to exact numbers. Furthermore, the Federal Circuit has provided that the use of "about" in a patent allows a patentee to avoid strict numerical boundaries. *Pall Corp. v. Micron Separations*, 66 F.3d 1211, 1217 (Fed. Cir. 1995) ("The use of the word 'about,' avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technologic and stylistic context."); *see also Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2006) (holding "about" to mean "approximately" in the context of varying ranges). Therefore, the Court adopts Astra's proposed construction of "about" as meaning "approximately."

5. "about" with respect to ranges of HPMC

This disputed term appears in Claims 3 through 9 and Claim 13 of the '437 Patent. Astra proposes that the term be defined as "approximately," which Astra argues is consistent with the term's plain and ordinary meaning. Handa, Accord, Anchen, and Osmotica simply propose that the term be given its plain and ordinary meaning. Biovail also proposes that the term be given its plain and ordinary meaning and that no construction is required. Torrent

takes no position.

For the reasons stated above in disputed term 4, the Court adopts Astra's proposed construction of the term.

6. "about" with respect to ranges of excipients other than HPMC

This disputed term appears in Claims 9 and 13 of the '437 Patent. Astra proposes that the term be defined as "approximately," which Astra argues is consistent with the term's plain and ordinary meaning. Handa, Accord, Biovail, Anchen, and Osmotica simply propose that the term be given its plain and ordinary meaning. Torrent takes no position.

For the reasons stated above in disputed term 4, the Court adopts Astra's proposed construction of the term.

7. "the total amount of [HPMC]"

This disputed term appears in Claim 3 of the '437 Patent. Astra and Osmotica propose that the term be defined as "the total amount of HPMC in the formulation," which they argue is consistent with the term's plain and ordinary meaning. Anchen proposes that the term mean "the total amount of HPMC set forth in subparts (a)-(d) of claim 3." Handa, Accord, Biovail, and Torrent take no position.

The Court adopts Astra and Osmotica's proposed construction of the term. There is nothing in the intrinsic evidence that limits the "total amount," in this context, to include only HPMC set forth in subparts (a)-(d) of Claim 3. This point is reinforced by the transition language of Claim 3, which defines the formulation as "comprising" one or more of the HPMCs listed in (a) through (d). The Federal Circuit has recognized that "comprising" is an

open-ended term, meaning that the invention can include additional elements. *Mars Inc. v. H.J. Heinz Co., et al.*, 377 F.3d 1369, 1375-76 (Fed. Cir. 2004). Therefore, the Court adopts Astra and Osmotica's claim construction here.

8. "a pH modifier"

This disputed term appears in Claims 11 through 13 of the '437 Patent. Astra and Osmotica propose that the term mean "one or more excipients capable of changing pH." Accord and Anchen propose that the term be construed as "an excipient that is a suitable organic acid or its alkali metal salt that modifies the pH of the environment in which the pharmaceutical formulation dissolves." Handa and Biovail propose that the term be given is plain and ordinary meaning, and that no construction is required. Torrent takes no position.

The Court adopts Astra and Osmotica's proposed construction of the term. Accord and Anchen's proposed construction improperly limits the term to the exemplary pH modifiers listed in the patent to narrow the meaning of the claim term. The language in the patent specification, providing for "pH modifiers which *include* suitable organic acids or alkali metal (e.g. lithium, sodium or potassium) salts thereof," supports the conclusion that "pH modifiers" are not limited to suitable organic acids or alkali metal salts, but instead simply *may be* a suitable organic acid or alkali metal salt. '437 Patent, col. 3, lines 65-67 (emphasis added).

9. "drying the mixture"

This disputed term appears in Claim 15 of the '437 Patent. Astra proposes a construction of "removing the water from the mixture." Biovail counters that the term should

be read to mean "drying the mixture obtained after performing step (a) then step (b), in that order." Handa, Accord, Anchen, and Osmotica propose that the term be given its plain and ordinary meaning and that no construction is required. Torrent takes no position.

The Court adopts the position of Handa, Accord, Anchen, and Osmotica. Astra asserts that "removing water from the mixture" is the plain and ordinary meaning of the term, but the Court is satisfied that "drying the mixture" is straightforward enough that it need not define the term beyond adopting its plain and ordinary meaning. Biovail's interpretation only introduces extraneous limitations to the claim and is therefore rejected.

10. "milling the dried mixture"

This disputed term appears in Claim 15 of the '437 Patent. Astra proposes that the term be defined as "pulverizing or grinding the dried mixture," which Astra contends is consistent with the term's plain and ordinary meaning. Astra further provides that the term include: "The step of 'milling the dried mixture' must follow the step of 'drying the mixture.'" Biovail proposes that the term mean "milling the dried mixture obtained after performing step (a), then step (b), then step (c), in that order. The step of 'milling the dried mixture' must follow the step of 'drying the mixture.'" Handa, Accord, Anchen, and Osmotica propose that the term be given its plain and ordinary meaning, and that no construction is required. Torrent takes no position.

The Court adopts Biovail's proposed construction of the term. The term appears in Claim 15, which details, in relevant part, a process for preparing a formulation which comprises:

> (a) mixing [quetiapine] or a pharmaceutically acceptable salt thereof, a gelling agent and other excipients;
> (b) wet granulating the mixed components;
> (c) drying the mixture;
> (d) milling the dried mixture;

'437 Patent, col. 16, lines 25-31. It is apparent from the language that the steps above must be performed in the order provided in the claim: wet granulating of mixed components is only possible after the components have been mixed; drying the mixture is likewise only possible after the mixture has been wet; and milling the dried mixture can only happen after the mixture has been dried. The Federal Circuit has likewise held that a claim is limited to a specific order when the "sequential nature of the claim steps is apparent from the plain meaning of the claim language and nothing in the written description suggests otherwise." *Tuna Processors, Inc. v. Hawaii Int'l Seafood, Inc.*, 327 Fed. Appx. 204, 209, 2009 WL 1084197, *4 (Fed. Cir. 2009) (quoting *Interactive Gift Exp., Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001). Therefore, the Court adopts Biovail's proposed construction here.

III. Conclusion

For the reasons set forth above, the terms at issue will be construed as indicated. An appropriate Order shall accompany this Opinion.

/s/ JOEL A. PISANO
United States District Judge

Dated: November 30, 2010